Claim for Priority

The Examiner's objection to Applicant's claim for priority is not understood. Applicant claims priority to U.S. Provisional Application 60/114,540, which was filed on December 29, 1998. Instant application was filed on December 29, 1999.

Sequences

The objection regarding sequences will be addressed when allowable subject matter is indicated.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-3 and 6-20 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Applicant respectfully traverses. Applicant urges that the specification contains a full written description of the invention, including the manner and different processes for making the invention, e.g., extraction, synthesis, etc., and method of using the invention, e.g., orally, subcutaneous injection, intravenous injection, and provides forms of availability, e.g., injectable fluid, tablet. The specification provides full direction, guidance and predictability of the result as shown by anti-HIV activity and lack of toxicity to enable one having ordinary skill in the art to make and use the invention. No undue experimentation is required.

The passage in the Noguchi et al. article relied upon by the Examiner is mere speculation on the part of the authors because they based their statement on limited experiments conducted on chickens. As noted in the last paragraph on page 61, a large scale trial for humans was being conducted to verify the HD antibody producing effect of N-Glycolylneuraminic acid ("NGNA"). The results of this trial in 90 human patients showed that NGNA failed to produce immunoresponse in humans. Noguchi et al., "Failure of Human Immunoresponse to N-Glycolylneuraminic Acid Epitope Contained in Recombinant Human Erythropoietin," Nephron, 72:599-603, 1996, attached as Exhibit 1.

Epogen (erythropoietin) is produced by Amgen and has been approved and in human use for over 15 years. It has been used in thousands of humans for treatment of anemia. Amgen has studied the HD antibody and other immunogenic effects of NGNA and has found no evidence of HD antibody formation in humans. *See* Information Sent to Applicant from Amgen, attached as Exhibit 2. It is asserted that no undue experimentation is necessary.

The Examiner bases the state of the prior art on a 1997 John Hopkins Guide to Medical Care of HIV patients. This guide is intended to discuss currently available FDA-approved drugs, that interfere with the viral replication after the virus has entered the cell by providing inhibition of reverse transcriptase or protease of the enzymes that is required by the virus to replicate. Applicant's specification teaches blocking of the virus entry into the cell by inhibition of the gp-120, an outer most protein covering of HIV that is essential for viral attachment to cells before the entry. *See* illustration attached as Exhibit 3. Not only is the mechanism distinct, this report is four years old, and was written as guide for the AIDS patients based on the knowledge available at that time. It is not a medical document for the researchers and scientists. Moreover, medical practitioners at John Hopkins with M.D. or M.D./Ph.D. degrees and researchers with M.D., Ph.D. or M.D/Ph.D. or equivalent degrees differ in opinion with scientists with similar qualifications from NIH, FDA and other academic institutions who even differ with scientists with similar degrees in the drug industry. *See, e.g.,* letters from NIH and others, attached as Exhibit 4. There is no undue amount of experimentation required.

It is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn and that claims 1-3 and 6-20 be indicated as allowable.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 16 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to further limit claim 1. Inasmuch as claim 1 recites "N-glycolylneuraminic acid or a derivative thereof" and claim 16 recites "N-glycolylneuraminic acid" only, it is believed that claim 16 further limits claim 1.

Rejection under 35 U.S.C. § 102(f)

After Applicant filed for patent protection, he disclosed his efforts under a secrecy agreement to Dr. Diefenbach, Dr. Larry Dayton, Dr. McGowan, Dr. Turk and 18 other scientists

at NIH. Thereafter, further disclosures were made to Dr. Turk, who offered to validate applicant's findings by independently testing the anti-viral activity of N-glycolylneuraminic acid using NIH contractor's laboratory, Southern Research Institute, under a confidentiality agreement with the applicant. *See* Communications, attached as Exhibit 5. Dr. Turk is an agent of the NIH and due to confidentiality agreements is obligated to maintain the secrecy of Applicant's disclosures. Similarly, Trevor O' Neil is a technician at Applicant's contractor lab who simply performed tests at the direction or advise of Applicant to validate Applicant's results. Dr. Turk and Mr. O'Neil are not the inventors or co-inventors and, as such, are not named. It is respectfully requested that the rejection under 35 U.S.C. § 102(f) be withdrawn and that claims 1-3 and 6-20 be indicated as allowable.

CONCLUSION

It is respectfully submitted that the foregoing remarks demonstrate that the application is in condition for allowance and prompt notification thereof is requested. If the prosecution of this application can be advanced by a telephone conference, the Examiner is request to call the undersigned at (202) 835-7526. Please charge any additional fees, or make any credits, to Deposit Account No. 13-3250, reference No. 36325-00600.

Respectfully submitted,

Date: December 26, 2001

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Date of Deposit __December 26, 2001_____
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

W. Jackson Matney, Jr.